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4/13/01

**UNITED STATES PATENT AND TRADEMARK OFFICE**

10/033055  
12/27/01  
PTO

Re: Application of: Ronald M. BURCH, *et al.*  
Serial No.: Not yet assigned  
Group No.: N/Y/K  
Filed: Herewith  
For: **SYNERGISTIC ANALGESIC COMBINATION OF  
OPIOID ANALGESIC AND CYCLOOXYGENASE-2  
INHIBITOR**

**INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents and Trademarks  
Washington, D.C. 20231

December 27, 2001

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-noted patent application.

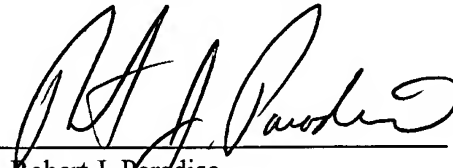
This Information Disclosure Statement is filed under 37 C.F.R. § 1.97 (b), before the mailing date of a first Office Action on the merits.

Additionally, in accordance with the provisions of 37 C.F.R § 1.98 (d), the references cited in the attached Form PTO-1449 have been previously submitted to the PTO or cited by the Examiner during the prosecution of parent application Serial No. 09/154,354, "Synergistic Analgesic Combination Of Opioid Analgesic And Cyclooxygenase-2 Inhibitor."

It is respectfully requested that the references cited in the accompanying Form PTO-1449 be considered and made of record. If any of the publications listed thereon are missing, the Examiner is requested to contact the undersigned so that a copy be promptly forwarded.

Respectfully submitted,  
DAVIDSON, DAVIDSON & KAPPEL, LLC

By



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FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:  
200.1079US

SERIAL NO.: 09/154,354

## LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): Ronald M. BURCH, et al.

FILING DATE:  
September 17, 1998

GROUP: 1614

J5879 U.S. PTO  
10/033056  
12/27/98

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5	8	5	9	2	5	7	01/12/9	Talley	548	247	08/14/96
	AB	5	8	6	3	9	2	2	01/26/99	Mayer, et al.	514	270	07/02/99
	AC	5	8	4	0	7	3	1	11/24/98	Mayer, et al.	514	289	08/02/95
	AD	5	8	6	9	4	9	8	02/09/99	Mayer, et al.	514	282	07/07/97
	AE	5	8	6	1	4	1	9	01/19/99	Dube, et al.	514	334	07/11/97
	AF	5	7	8	9	4	1	3	08/04/98	Black, et al.	514	255	01/21/97
	AG	5	6	0	4	2	6	0	02/18/97	Guay, et al.	514	605	11/04/93
	AH	5	4	5	8	8	7	9	10/17/95	Singh, et al.	424	400	09/30/94
	AI	5	5	1	6	8	0	3	05/14/96	Raffa	514	570	03/01/95
	AJ	5	8	4	3	4	6	8	12/01/98	Burkoth, et al.	424	448	05/13/96
	AK												

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AL	<u>Differential Inhibition of Cyclooxygenase-1 (COX-1) and -2 (COX) By NSAIDS: Consequences on Anti-Inflammatory Activity Versus Gastric and Renal Safety, M. Pairet, et al., Inflammopharmacology 4; 61-70, (1996).</u>
AM	<u>Differential effects of inhibitors of cyclooxygenase (cyclooxygenase 1 and cyclooxygenase 2) in acute inflammation, Derek W. Gilroy, et al. European J. Pharm 355 pp 211-217, (1998).</u>
AN	<u>Cyclooxygenases 1 and 2, J.R. Vane, et al. Annu. Rev. Pharmacol. Toxicol. 38: 97-121, (1998).</u>
AO	<u>Analysis of the effects of cyclooxygenase (COX)-1 and COX-2 in spinal nociceptive transmission using indomethacin, a non-selective COX inhibitor, and NS-398, a COX-2 selective inhibitor, Tatsuo Yamamoto, et al. Brain Research 739:104-110, (1996).</u>
AP	<u>Comparative Analgesic Efficacy of Nimesulide and Diclofenac Gels after Topical Application on the Skin, S. Sengupta, et al., Skin Pharmacol. And Applied Skin Phys. 11: 273-278, (1998).</u>
AQ	<u>Carrageenan-induced hyperalgesia is associated with increased cyclo-oxygenase-2 expression in spinal cord, Cariona Hay and Jacqueline de Bellerche, NeuroReport 8, 1249-1251, (1997).</u>
AR	<u>The Mechanisms of Action of NSAIDs in Analgesia, Jeremy N. Cashman, Drugs 52 Supp. 5:13-23, (1996).</u>
AS	<u>Differential effects of inhibition of isoforms of cyclooxygenase (COX-1, COX-2) in chronic inflammation, D.W. Gilroy, et al. Inflamm. Res. 47: 79-85, (1998).</u>
AT	<u>Constitutive Cyclooxygenase (COX-1) and Inducible Cyclooxygenase (COX-2): Rationale for Selective Inhibition and Progress to Date, Don E. Griswold and Jerry L. Adams, Medicinal Research Reviews, Vol. 16, No. 2, pp. 181-206, (1996).</u>

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1079US		SERIAL NO.: 09/154,194	
<b>LIST OF PRIOR ART CITED BY APPLICANT</b> (Use several sheets if necessary)				APPLICANT(S): Ronald M. BURCH, et al.			
				FILING DATE: September 17, 1998		GROUP: 1614	
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	BA						
	BB						
	BC						
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	BK						
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES
	BL						
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	BM	Cyclooxygenase in biology and disease, Raymond N. Dubois, et al., FASEB J. Vol. 12 pp. 1063-1073 (1998).					
	BN	Pharmacology of Meloxicam, A new Non-Steroidal Anti-Inflammatory Drug With An Improved Safety Profile Through Preferential Inhibition of COX-2, G. Engelhardt, British J. Rheumatology, 35 (supp 1):4-12, (1996).					
	BO	Cyclooxygenase 1 Contributes to Inflammatory Responses in Rats and Mice: Implications for Gastrointestinal Toxicity, John L. Wallace, et al. Gastroenterology, 115:101-109 (1998).					
	BP	Distinct isoforms (COX-1 and COX-2) of cyclooxygenase: possible physiological and therapeutic implications, M. Pairet and G. Engelhardt, Fundam. Clin. Pharmacol. 10:1-15, (1996).					
	BR	Involvement of Prostaglandins Produced by Cyclooxygenase-1 in Murine Visceronoception Induced by Phenylquinone, Hidenobu Kusuvara, et al. Prostaglandins 55: 43-49, (1998).					
	BS	Effect of COX-1 and COX-2 Inhibition on Induction and Maintenance of Carrageenan-Evoked Thermal Hyperalgesia in Rats. D. Dirig, et al. J. Pharmacol. And Experimental Therapeutics Vol285, No. 3, pp 1031-1038.					
	BT						
EXAMINER				DATE CONSIDERED			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

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FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1079US		SERIAL NO.: 09/154,354	
LIST OF PRIOR ART CITED BY APPLICANT  (Use several sheets if necessary)				APPLICANT(S): Ronald M. BURCH, et. al.  FILING DATE: September 17, 1998  GROUP: 1627			
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL	AA	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA						
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FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
	AE	9 9 0 7 4 1 3	2/18/99	WO			
	AF	9 9 3 2 1 1 9	7/1/99	WO			
	AG						
	AH						
	AI						
	AJ						
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AK	Effect of meloxicam on postoperative pain after abdominal hysterectomy, J.P. Thompson et al. <i>British Journal of Anaesthesia</i> 84 (2) 151-4 (2000).					
	AL	Intrathecal cyclooxygenase inhibitor administration attenuates morphine antinociceptive tolerance in rats. C.S. Wong et al. <i>British Journal of Anaesthesia</i> 85 (5) 747-51 (2000).					
	AM	Cyclooxygenase inhibitors increase morphine effects on mesolimbic dopamine neurons, M. Melis, et al. <i>Eur. J. Pharmacology</i> 387 (1) R1-R3 (2000).					
	AN	Synergistic antiallodynic effects of spinal morphine with ketorolac and selective COX1- and COX2-inhibitors in nerve-injured rats, J.M. Lashbrook, et al. <i>Pain</i> 82 (1) 65-72 (1999).					
	AO	Enhancement of opioid inhibition of gaba-ergic synaptic transmission by cyclo-oxygenase inhibitors in rat periaqueductal grey neurones, Vaughn et al. <i>British Journal of Pharmacology</i> 123 (8) 1479-81 (1998).					
	AP						
	AQ						
EXAMINER				DATE CONSIDERED			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant							

Jc879 U.S. PTO  
 10/033055  
 12/27/01



FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:  
200.1079US

SERIAL NO.: 09/154,834

## LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): Ronald M. BURCH, et al.

FILING DATE:  
September 17, 1998

GROUP: 1614

10/03/05  
12/27/01  
10/03/05  
12/27/01

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	3	8	0	0	0	4	1	03/26/74	Miller, et al.	424	273	03/02/71
	AB	4	3	2	2	4	2	7	03/30/82	Buyinski, et al.	424	260	04/16/81
	AC	4	3	3	8	3	2	4	06/06/82	Gardocki	424	266	03/17/81
	AD	4	4	0	4	2	1	0	09/13/83	Schmidt	424	260	06/30/82
	AE	4	4	0	7	8	0	4	10/04/83	Schmidt	424	260	06/30/82
	AF	4	4	0	7	8	0	5	10/04/83	Schmidt	424	260	06/30/82
	AG	4	4	6	4	3	7	6	08/07/84	Sunshine, et al.	424	253	10/11/83
	AH	4	4	8	6	4	3	6	12/04/84	Sunshine, et al.	424	253	03/11/83
	AI	4	4	8	9	0	8	0	12/18/84	Lomen	424	260	12/06/82

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	AJ	2	0	2	3	3	4	9	02/18/91	Canada	A61K	31/44		
	AK	0	2	7	4	8	4	5	07/20/88	EP (A1)	A61K	31/19		
	AL	0	3	8	8	1	2	5	09/19/90	EP (A1)	A61K	31/485		

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AM	Pharmacokinetics and Drug Input Characteristics for a Diclofenac-Codeine Phosphate Combination Following Oral and Rectal Administration A. Hansen, et al. Arzneim.-Forsch./Drug Res. 46 (I), 57-63 (1996).
	AN	Comparison of a Standard Ibuprofen Treatment Regimen with a New Ibuprofen/Paracetamol/Codeine Combination in Chronic Osteo-arthritis G. K. Vlok, et al. Univ. Stellenbosch and Tygerberg Hospital, Dept. Orthopaedic Surg. pp 3-6, (1987).
	AO	
	AP	
	AQ	

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FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 200.1079US		SERIAL NO.: 09/154,354								
LIST OF PRIOR ART CITED BY APPLICANT				APPLICANT(S): Ronald M. BURCH, et al.										
(Use several sheets if necessary)														
				FILING DATE: September 17, 1998		GROUP: 1614								
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	BA	4	5	6	7	1	8	3	01/28/86	Sunshine, et al.	514	264	12/12/83	
	BB	4	5	6	9	9	3	7	02/11/86	Baker, et al.	514	282	02/11/83	
	BC	4	5	7	1	4	0	0	02/18/86	Arnold	514	282	12/18/84	
	BD	4	5	8	7	2	5	2	05/06/86	Arnold	514	282	12/18/84	
	BE	4	6	1	9	9	3	4	12/28/86	Sunshine, et al.	514	277	07/08/85	
	BF	4	6	9	0	9	2	7	09/01/87	Voss, et al.	514	282	02/03/86	
	BG	4	8	3	9	1	7	6	06/13/89	Pahkhanian, et al.	424	465	12/08/87	
	BH	4	8	4	4	9	0	7	07/04/89	Elger, et al.	424	465	08/14/86	
	BI	4	9	2	7	8	5	4	05/22/90	Sunshine, et al.	514	570	08/21/89	
	BJ	5	1	6	4	3	9	8	12/17/92	Sims, et al.	514	282	04/01/91	
	BK	5	1	9	0	9	4	7	03/02/93	Riess, et al.	514	282	08/16/91	
	BL	5	2	4	0	6	9	4	08/31/93	Gwaltney, Jr.	424	45	12/19/91	
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	BM	0	0	6	8	8	3	8	06/25/82	EP (A1)	A61K	31/485		
	BN	0	0	6	8	8	3	8	06/25/82	EP (B1)	A61K	31/485		
	BO	2	0	8	1	6	0	4	05/01/95	Canada	A61K	031/135		
	BP													
	BQ													
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
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	BT													
EXAMINER										DATE CONSIDERED				
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FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:  
200.1079US

SERIAL NO.: 09/154,324

## LIST OF PRIOR ART CITED BY APPLICANT

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APPLICANT(S): Ronald M. BURCH, et al.

FILING DATE:  
September 17, 1998

GROUP: 1614

10/033055  
12/27/01

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5	4	0	9	9	4	4	04/25/95	Black, et al.	514	359	03/12/93
	AB	5	4	3	6	2	6	5	06/25/95	Black, et al.	514	420	11/12/93
	AC	5	5	1	0	3	6	8	04/23/96	Lau, et al.	514	419	05/22/95
	AD	5	5	2	1	2	1	3	05/28/96	Prasit, et al.	514	443	08/29/94
	AE	5	5	5	0	1	4	2	08/27/96	Ducharme et al.	514	365	05/08/95
	AF	5	5	5	2	4	2	2	09/03/96	Gauthier, et al.	514	368	01/11/95
	AG	5	6	0	4	2	5	3	02/18/97	Lau, et al.	514	415	05/22/95
	AH	5	6	3	9	7	8	0	06/17/97	Lau, et al.	514	419	05/22/95
	AI												

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	AJ													
	AK													
	AL													

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AM	Anti-inflammatory Drugs and Their Mechanism of Action J.R. Vane, et al. Inflamm. Res. 47, Supplement 2 (1998).
	AN	
	AO	
	AP	
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